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308/2E
December 19, 2001

Dow AgroSciences

National Organic Standards Board
c/o Robert Pooler, Agricultural Marketing Specialist
USDA/AMS/TM/NOP, Room 2510-So.
Ag Stop 0268, P.O. Box 96456
Washington, D.C. 20090-6456

PETITION FOR THE LISTING OF SPINOSAD ON THE USDA NATIONAL LIST OF ALLOWED AND PROHIBITED SUBSTANCES

The Organic Foods Production Act of 1990, as amended, established a National List of Allowed and Prohibited Substances (National List) which identifies the synthetic substances that may be used, and the nonsynthetic substances that cannot be used, in organic production and handling operations. The Act also provides a mechanism to petition the National Organic Standards Board to evaluate a substance for inclusion on or removal from the National List. With this petition, Dow AgroSciences requests review of the fermentation product spinosad for consideration and, if appropriate, listing on the Proposed National List of Organic substances for inclusion on:

1. The list of allowed substances for use in organic crop production.
2. The list of allowed substances for use in organic livestock production.

Spinosad is a naturally derived product produced through the fermentation of the bacteria *Saccharopolyspora spinosa*. The *S. spinosa* bacterium is a naturally occurring organism and is not genetically engineered. It is our understanding that the national approved list is for active ingredients only. Listing of spinosad as an approved active ingredient will facilitate the future and subsequent assessments of end-use formulations containing spinosad by appropriate state organizations. Only end-use formulations that contain previously certified organic components or EPA list-4 inert components would be submitted to state certification organizations.

Spinosad is an EPA registered active ingredient. Extensive risk assessments and safety standards are already in place, such as an established ADI standard for human exposure. Thus, spinosad has been fully evaluated for use on multiple crops with large margins of safety that would be important to the organic grower. Additionally, there are numerous public literature resources available for spinosad. Accordingly, there is a large amount of product knowledge behind spinosad that could now become useful to the organic grower.

We appreciate the time and effort that the Department of Agriculture, Agricultural Marketing Services, invests in the review of petitions for organic status. Please feel free to contact me at my phone number or e-mail address below if you have any questions on any aspect of this petition.

Sincerely,

John J. Jachetta, Ph.D.
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Petition for the Inclusion of Spinosad on the National Organic Standards Board List of Approved Organic substances.

With this petition, Dow AgroSciences LLC is requesting the evaluation of spinosad for inclusion on:

1. The list of allowed substances for use in organic crop production.
2. The list of allowed substances for use in organic livestock production.

The following information addresses the Department of Agriculture, Agricultural Marketing Services Notice of Guidelines and Call for National List Petitions as discussed in the July 13, 2000 Federal Register Notification (Volume 65, 43259 – 43261).

Spinosad for Insect Pest Management

1. The common name for the substance:

Spinosad is isolated from the Actinomycetes species *Saccharopolyspora spinosa.* This organism produces a broth, which naturally contains a mixture of structurally similar factors, or spinosyns. The term "spinosad" refers to isolated technical material, which predominantly contains two spinosyn factors that are both active insecticides. These factors have been designated spinosyn A and spinosyn D and together they comprise 90% of the technical material in a ratio of approximately 85% A:15% D. Extremely small quantities of other naturally occurring and structurally similar spinosyn factors (Factors A1, B, B(D), C, E, F G, H, and K), along with other minor fermentation byproducts and components, also occur.

ISO common name	Spinosyn A and Spinosyn D
Chemical name	Spinosyn A and Spinosyn D
IUPAC name	Spinosyn A: (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,6,7,9,10, 11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-8-oxacyclododeca[*b*]*as*-indacene-7,15-dione Spinosyn D: (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,6,7,9,10, 11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-8-oxacyclododeca[*b*]*as*-indacene-7,15-dione
Chemical Abstract name:	Spinosyn A: 2-((6-Deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)oxy)-13-((5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl)oxy)-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,

14,16a,16b-tetradecahydro-14-methyl-1H-as-indaceno(3,2-d)oxacyclododecin-7,15-dione

Spinosyn D: 2-((6-Deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)oxy)-13-((5-(dimethylamino)tetrahydro-6-methyl-2H-pyran-2-yl)oxy)-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14,16a,16b-tetradecahydro-4,14-dimethyl-1H-as-indaceno(3,2-d)oxacyclododecin-7,15-dione

Synonyms: DE-105; XDE-105; DE-105 Factors A and D

2. The manufacturer's name, address and telephone number.

Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

Contact: John Jachetta, Ph.D.
Phone: (317) 337-4686
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3. The intended or current use of the substance:

Spinosad is used as an insecticide. It is a naturally derived fermentation product that has demonstrated insect control activity against a large number of pests including members of the insect orders Lepidoptera, Coleoptera and Thysanoptera.

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode-of-action must be described.

Spinosad is an insect control product that can be formulated for control of some foliage feeding pests including lepidopterous larvae (worms or caterpillars), thrips, Colorado potato beetles and leafminers infesting a number of crop plants, including: almonds, apples, cereal grains, citrus, cole crops, corn, sweet corn, cotton, cucurbits, fruiting vegetables, grain amaranth, leafy vegetables, potatoes and tuberous and corm vegetables, sorghum, soybeans, stone fruit, succulent and dry beans and peas, and tree farms or plantations. Spinosad based products were first introduced during 1997. By January 2001, spinosad based products have been used in 32 countries and on 200+ crops and ornamentals. A high level of efficacy, coupled with excellent compatibility with nontarget insects, has resulted in the wide acceptance of this fermentation product for insect control in many crop production areas.

Over 10 million acre applications were made during 2000. End-use formulations of spinosad are applied as a suspension concentrate to the foliage of plants. The rate of spinosad active ingredient applied to crop plants varies by pest and crop and extends from 0.023 lb. a.i./acre to 0.156 lb. a.i./acre. Solid or liquid bait can be used for fruit fly and fire ant control at rates of approximately 0.00029 lb a.i./acre on and around crop plants.

Spinosad is formulated as a pour-on product for the control of chewing and sucking lice on lactating dairy cattle, and for the control of lice and horn flies on beef and non-lactating dairy cattle at a rate of 2 mg/kg body weight. It may also be diluted and used as a sprayable product for the control of lice and horn flies on beef and dairy cattle (lactating and non-lactating) to be used by applying 1-2 qt per animal of a 400 ppm spray on agricultural premises.

Spinosad is supported by tolerances established by the U.S. EPA on most crop plants and crop plant groups, including a wide range of minor and specialty crops. Additionally, tolerances exist for meat and mike products. Application of spinosad is supported by 40CFR 180.495.

This request is for Spinosad Technical only, the isolated active principal derived from the fermentation of *Saccharopolyspora spinosa.* It is understood that only end-use formulations that contain certified organic components or EPA list-4 inert components will be considered for organic crop or livestock production.

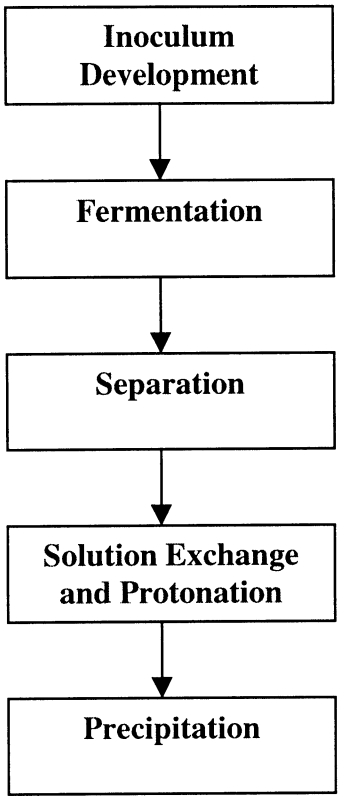
Spinosad is a crop protection product for the control of certain insects infesting crops and livestock. Spinosad is not used in the handling or processing of agricultural products.

5. **The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product.**

Spinosad Manufacturing Process:

A fermentation process uses a strain of the Actinomycetes species *Saccharopolyspora spinosa* to produce Spinosad Technical. The fermentation product primarily contains a mixture of two structurally similar molecules which are both active insecticidally and have been designated spinosyn A and spinosyn D. Spinosad Technical typically contains spinosyns A and D in a ratio of approximately 85%A:15%D. After the fermentation is complete, Spinosad Technical is recovered from the fermentation broth by a solvent extraction, followed by solvent exchange/protonation and precipitation. All processing steps are performed in a modern facility that was designed to minimize the potential for environmental impact associated with manufacture. The block diagram in Figure 1 depicts the major steps of the process.

Figure 1. Spinosad Technical Manufacturing Process



A description of each key step of the process is given. The description includes the product stewardship efforts to recycle and minimize environmental impact from the manufacturing process.

Inoculum Development

A preserved culture of *S. spinosa* is used to inoculate an appropriate quantity of vegetative medium V_i. After three to four days of incubation, the growth from the media is used to inoculate a seed fermentor. The stirred seed fermenter is allowed to grow until a desired oxygen uptake rate is reached. The seed inoculum is then used to inoculate the fermenter stage.

The vegetative medium, V_i, contains naturally derived proteins, carbohydrates, and minerals such as trypticase soy broth, yeast extract, glucose, and magnesium sulfate. The seed fermenter contains similar ingredients to V_i as well as ammonium chloride, methyl oleate, calcium carbonate, and potassium phosphate.

Fermentation

The process is carried out in large fermentors charged with water and the fermentation media. The fermentation media contains a mixture of natural proteins, carbohydrates, oils,

and minerals such as corn solids, cottonseed flour, soybean flour, glucose, methyl oleate, and calcium carbonate. The fermentor is sterilized and inoculated with the seed medium and allowed to grow. Due to the presence of soluble proteins, antifoam is added to the fermenter as needed. Air used in the process is treated via catalytic incineration to eliminate the release of odors from the site. This also assures that no live culture is released to the environment. The incinerators are licensed to operate at an efficiency of 99+ % destruction.

Separation

Spinosad Technical is essentially insoluble in the fermentation media. After the fermentation is complete, spinosad is separated from the fermentation media into an extraction solution; soluble proteins and the biomass are separated from the extraction solution by centrifugation or filtration. Solution containing Spinosad Technical is forwarded to a solution exchange/protonation step.

The spent fermentation media and biomass solids contain residual proteins, oils and carbohydrates, as well as excess water and some residual extraction solution. The excess water and residual extraction solution are recovered via multi-stage distillation. Greater than 99.9% of the extraction solution is recovered and recycled for subsequent use. Prior to discharge to the environment, the excess water is purified through the combination of activated carbon, anaerobic and aerobic digestion, in accordance with all state and federal laws. The non-hazardous biomass concentrate is then stabilized with lime and interred within licensed landfills. Even less impactful disposal methods such as land application of the biomass are under investigation.

Solution Exchange/Protonation

The extraction solution containing Spinosad Technical is blended with acidified water to separate Spinosad Technical and prepare the material for precipitation from the aqueous phase.

The spent extraction solution is purified for recycle via multi stage distillation. The purified extraction solution is then recycled directly into the process. The non-volatile residue from the distillation contains oils and other non-hazardous materials from the fermentation. This material is collected and stored for intermittent disposal via incineration at a licensed facility.

Precipitation

Base is added to the aqueous phase to neutralize the solution, causing spinosad crystals to precipitate from the solution. The Spinosad Technical is separated from the liquid by centrifugation. The wet cake is washed and dried to remove water and then packaged for shipment to formulation sites.

Spinosad Technical for organic use contains only the spinosyn factors (90%) and residual nutrient broth components (10%); no additional or non-organic components are present in this product.

6. **A summary of any available previous reviews by state or private certification programs or other organizations of the petitioned substance.**

October 7, 1998: Organic Materials Review Institute (OMRI) staff and Review Panel response to Dow AgroSciences application for organic certification of the end-use formulation, Success* Naturalyte* insect control (Appendix A). OMRI denied this petition, stating that:

1. "The Review Panel first considered the information of the active ingredient, spinosad, which they determined to be non-synthetic and therefore allowed for organic production."
2. "However, the Review Panel recommended that the formulation be prohibited for use in organic production." The decision to deny the Success formulation was based on EPA inerts list-3 components in that formulation.

We are petitioning NOSB to include the active principle (spinosad) isolated from *S. spinosa* on the National List for use in organic crop and livestock production. Listing of the active ingredient will facilitate the subsequent assessment of end-use formulations containing spinosad by appropriate state organic certification organizations. Only those end-use formulations that contain previously certified organic components or EPA list-4 inert components would be submitted to state certification organizations.

History of Organic Spinosad Actions

Agency/Date	Review	Action
OMRI October 7, 1998	Review of Success formulation	Not approved due to concerns over inerts
OMRI October 7, 1998	Review of Spinosad Technical (same October 7, 1998 review as above)	Determined spinosad to be non-synthetic and allowable for organic production
State of Colorado February 1999	Local request	SpinTor* 2SC Naturalyte* insect control added to approved list
State of Texas July 2000	Request from state to Dow AgroSciences	State approved temporary use on organic cotton
State of California May 9, 2001	Grower request	Temporary approval of the GF-120 Fruit Fly Bait
Tunisia	Local request	Added to Country approved list
Switzerland	Local request	Added to Country approved list
USDA	This application for technical	Application submitted 2001
OMRI	GF-120 and Fire Ant bait	Planned submission in 2001

7. **Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.**

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This petition requests the listing of Spinosad Technical material on the USDA National List of Allowed or Prohibited Substances.

The technical formulation registered in the U.S. is Spinosad Technical (EPA Registration Number 62719-266)

Spinosad is also registered as a number of end-use products; those products and EPA Registration Numbers are listed below. Organic certification for those formulations containing only organic components will be requested through state agencies such as OMRI; this request will initially include the fire ant and fruit fly baits, which contain only EPA List-4 inerts, but may later include new formulations specifically designed for the organic grower. Development of specific organic formulations will be facilitated by the listing of Spinosad Technical.

Name	EPA Registration Number
Tracer* Naturalyte* insect control	62719-267
Success Naturalyte insect control	62719-292
Spinosad SC insecticide	62719-296
SpinTor 2SC Naturalyte insect control	62719-294
Conserve* SC Turf and Ornamental insect control	62719-291
Spintech* insect solution (originally Precise* insect solution)	62719-297
Conserve Fire Ant Bait insect control	62719-304
Conserve Professional Fire Ant Bait insect control	62719-329
NAF-127 (Internal Formulation Number)	62719-282
NAF-371 (Internal Formulation Number)	62719-314
GF-120 Fruit Fly Bait	Registration pending
ELANCO animal health product	Registration pending

8. The Chemical Abstract Service (CAS) number.

CAS No. Spinosyn A: 131929-60-7
Spinosyn D: 131929-63-0

9. The substance's physical properties and chemical mode-of-action including

(a) **Chemical interactions with other substances, especially substances used in organic production;**

Spinosad-based products are frequently tank-mixed with other crop protection products and fertilizers by current end-users. Spinosad formulations are universally accepted as being highly compatible and have no phytotoxicity concerns. As part of research and development, Dow AgroSciences has conducted numerous compatibility studies and found no unusual compatibility issues. These tests included several Bt (*Bacillus thuriengenesis*) products, organic sulfur dusts, long chain fatty acids (Impede and Safer

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Soaps) and vegetable oils. However, because it is impossible to test all combinations, water volume concentrations and water sources, Dow AgroSciences recommends a standard jar test before preparing product tank-mixes for the first time. Additionally, a standard mixing order is recommended to avoid certain compatibility problems that occur with some products but that are not specific to spinosad. Directions for the jar test and mixing order are specified on the labels.

(b) Toxicity and environmental persistence:

Organic agriculture embraces methods that minimize impact on the ecological balance of natural systems. Environmental burden from pesticides is reduced when compounds break down rapidly after application and, thus, do not have an opportunity to accumulate in unintended environmental compartments such as groundwater or living organisms such as fish. One of the most important attributes of spinosad is its rapid degradation by multiple mechanisms.

Spinosad is non-persistent with observed overall field dissipation half-lives ranging from 0.3 to 0.5 days. Primary pathways of degradation are photolysis by sunlight and microbial breakdown. Breakdown of spinosad exposed to sunlight has been observed in all key environmental compartments: treated plant surfaces (half-lives of 2 to 16 days), water (half-life <1 day) and on bare field soil (<1 day). In the absence of sunlight, spinosad still undergoes microbial decay; laboratory studies conducted in aerobic soil in the dark indicate a bi-phasic degradation pattern with an initial half-life on the order of two weeks. A study under forestry conditions resulted in 50% dissipation times (DT_{50} values) from 2.0 to 7.8 days; these results illustrate the timely breakdown of spinosad even with attenuated light. There are currently no approved aquatic uses of spinosad, but in the event of unintended drift or trace run-off to a pond, spinosad would degrade quite rapidly because of its documented short persistence in water.

Environmental burden from pesticides is also reduced when compounds are not highly mobile. Compounds that stay put do not have an opportunity to move to groundwater or unintended habitats. Spinosad is moderately to strongly sorbed by soil particles and, therefore, it is relatively immobile. K_d values for spinosad range from 4.3 to 323 mL/g depending on soil type and length of soil contact. These relatively high K_d coefficients indicate that spinosad is attracted to the solid phase in soils. Both laboratory soil column studies and field studies have confirmed that spinosad does not leach in soil.

Compounds are considered environmentally friendly when they demonstrate selectivity. Selective compounds are efficacious for the target pest, but demonstrate low toxicity to non-target organisms. For spinosad, numerous toxicity tests demonstrate that the toxicity of spinosad to most non-target organisms is generally low, including mammals, birds, earthworms, fish, and most aquatic species.

When a compound is not totally selective from the laboratory toxicity tests, it can still be determined as safe for use depending on the intended use pattern. In laboratory tests, spinosad has demonstrated toxicity to some aquatic organisms. However, due to the rapid

dissipation of spinosad, the actual risk from in-field use has been demonstrated to be very low. The EPA has determined when the exposure of spinosad to aquatic organisms is calculated using environmental fate transport models to predict off-site environmental concentrations, actual impact under field conditions for aquatic organisms is unlikely. Likewise, spinosad is inherently toxic to bees under laboratory conditions, but toxicity of residue studies and field studies indicate that under actual use conditions, the impact on bees is eliminated once the sprayed material has dried.

(c) Environmental impacts from its use or manufacture;

It is important to note that although spinosad is produced on a large scale, the production is not synthetic. Production through fermentation is a natural process - the material produced is by the organism and remains chemically unchanged by the fact that the organisms happen to be housed in large production containers. The fermentation media consists exclusively of naturally derived proteins, carbohydrates, and minerals such as, trypticase soy broth, yeast extract, glucose, and magnesium sulfate. While spinosad is extracted from the fermentation broth and bacteria, all spent solvent is purified for recycle and re-use via multi-stage distillation. The purified solvent is then recycled directly into the process. The non-volatile residue from the distillation contains oils and other non-hazardous materials co-extracted with the spinosad from the fermentation. This material is collected and stored for intermittent disposal via incineration at a licensed facility. The spinosad technical manufacturing process is described in detail in section 5. Spinosad's low potential for environmental impact is discussed further in Section 9(b) under Toxicity and Environmental Persistence.

Spinosad has been recognized at both the federal and state level for its positive environmental profile as an insect control product. In 1997, California gave spinosad the first state Special Local Need registration ever granted in the U.S. specifically for pollution prevention in the control of insect pests infesting almonds. Spinosad was federally registered in 1997 under EPA's Reduced Risk expedited review program and was the first insect control product registered under FQPA with a tolerance. In 1999, spinosad and its fermentation-based manufacturing process were awarded the Presidential Green Chemistry Award. This award was instituted in 1995 by President Clinton to promote pollution prevention and industrial ecology in partnership with the agricultural sciences industry. The EPA administers this award program and views it as an opportunity to recognize fundamental breakthroughs in cleaner, smarter products and manufacturing processes. This award recognizes products and processes that incorporate the concepts of Green Chemistry into manufacturing design and crop protection. Organic growers would view a Green Chemistry product as an asset.

(d) Effects on human health;

Numerous mammalian toxicology studies have been conducted and the results demonstrate a highly favorable profile for spinosad. Spinosad displays low acute toxicity to mammals. Low toxicity is associated with high LD_{50} values. The rat oral LD_{50} is 3738 mg/kg for males and >5000 mg/kg for females, and the mouse oral LD_{50} is >5000 mg/kg. The rabbit dermal

LD_{50} is >5000 mg/kg and the rat inhalation LC_{50} is >5.18 mg/L air (highest limit tested). Spinosad is slowly and poorly absorbed through skin. Spinosad has also been tested for long-term effects and has not been found to cause tumors in laboratory animals or to have any potential to cause neurotoxicity. The U.S. EPA determined there is no special sensitivity of young or unborn children to spinosad. Spinosad has been tested in a battery of genotoxicity studies and has no mutagenic potential.

Toxicity tests are used to set worker safety standards. Rapid degradation in field and low mammalian toxicity translates to minimal requirements for the end-user. For agricultural uses that fall under the Worker Protection Standard (WPS), all formulations of spinosad are labeled with the most minimal WPS worker protective equipment and re-entry interval allowed by law.

(e) Effects on soil organisms, crops, or livestock.

Laboratory studies have been performed to investigate the potential impact of spinosad on soil environments. Specifically, effects of spinosad were investigated for earthworms, soil nitrogen transformation processes (ammonification and nitrification) and soil microbial respiration. Results for soil indicated that spinosad would not be expected to cause any significant effect on either soil microflora respiration or nitrogen transformation in soils when applied at either the field use-rate (540 g a.i./ha) or 10 times that rate (5,400 g a.i./ha). For earthworms, tests with both pure spinosad and spinosad formulated as Tracer demonstrated large margins of safety for earthworms. The LC_{50} value for Tracer on earthworms was greater than 2000 mg/kg; spinosad as the pure active ingredient had an LD_{50} greater than 970 mg/kg.

Spinosad has also been evaluated on representatives of all crop groups and a number of weed species. In all cases, spinosad has been found to be nontoxic to plant species.

Spinosad is metabolized and excreted by mammals and, therefore, does not bioaccumulate in living tissues. Metabolism studies in poultry and ruminant animals show no residues of spinosad or its metabolites in meat, milk, or eggs when applied at agronomic rates.

Spinosad has low mammalian toxicity and is safe to livestock. Registrations for topical use on livestock for fly control in cattle and sheep have been established in Australia and are currently under review in the U.S.

10. Safety information about the substance.

A Material Safety Data Sheet (MSDS) is attached in Appendix B. No substance report from the from the National Institute of Environmental Health Studies was available.

11. Research information about the substance that includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies that

present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.

Spinosad is a relatively new molecule and received its first registration in 1997. With the recent introduction and normal delay in publications, there have been no review type articles written either supporting or contrasting spinosad. However, the unique natural origin, considerable utility against key pests, and favorable safety profiles have resulted in thousands of individual studies within and outside of Dow AgroSciences. Appendix C includes a copy of a literature search of all published information available on March 21, 2001. This bibliography includes 810 publications. The majority of these are by universities publishing efficacy data on target pests. Also, numerous articles were published as an offshoot of the official studies conducted on residue and non-target safety during the registration process. Please feel free to request a more focused literature search if needed.

A few specific articles are attached to provide a representation of what is available in the published literature (Appendix D).

1. Spinosad - a case study: an example from a natural products discovery programme. Pest Management Science. 56:696-702. 2000. An overview of discovery and source.
2. Midwest Biological Control News. 6(3). 1999. A listing of products compatible with biological control indicating spinosad compatible and similar to current organic standards.
3. Arthropod Management Tests. Volume 25. 2000. A collection of efficacy trials indicated the effectiveness of Spinosad.
4. Down to Earth, Vol. 52(1) 1997. A collection of articles on spinosad
5. Spinosad Technical Bulletin. 2000.

12. A "Petition Justification Statement" which provides justification for the inclusion of spinosad on the National List.

<u>Spinosad should compliment cultural and biological controls, not replace them</u>

Spinosad is a natural occurring metabolite that is produced in an environmentally friendly manner. The reason it was not included on the initial NOSB list was due to its recent discovery and availability. It is a very selective microbial product with activity almost limited to a few pest insects. However, for those insects on which it does work, spinosad will provide rapid activity and economic control. This selectivity and rapid activity will provide a powerful IPM tool to the organic farmer. Less effective products have to be applied in large doses (which disrupt the environment) and on a preventive basis. The organic grower, who knows there is an effective product if pests exceed economic thresholds, can defer treatments and allow low numbers of pests and their predators to exist. If a pest's reproductive capacity exceeds those of predators and parasites, the growers can apply the rapidly acting spinosad to manage pest populations with no to minimal effects on predators and parasites.

Expansion of organic agriculture

Organic agriculture has been less successful in southern and subtropical environments where insect pests can reproduce more rapidly. The addition of spinosad to the organic toolbox should help in these areas, bring more variety to the produce available, and extend the time when it can be produced.

Resistance management

Insect populations have demonstrated the ability to develop resistance to synthetic and organic products (Bt) when they are repeatedly challenged. Spinosad products will allow organic growers to rotate products such as spinosad and Bt to prolong the utility of both actives.

Control not available

Spinosad products will allow organic growers to control pests that have no suitable organic control product today. Uncontrolled pests include the imported fire ant and fruit flies (Med-fly, apple maggot, blueberry maggot, Mex-fly, etc.). Such pests are often exotic in nature and have no natural control agents in the U.S. Some spinosad formulations also control thrips and leafminers that transmit plant viruses and have few suitable control tactics.

Appendix A

OMRI

October 7, 1998

Gary Thompson
Dow AgroSciences
9330 Zionsville Rd.
Indianapolis, IN 46268

Dear Mr. Thompson:

Thank you for applying to the Organic Materials Review Institute (OMRI) for brand name product review. OMRI's staff and Review Panel have reviewed the product, Success Naturalyte Insect Control. The Review Panel first considered the information on the active ingredient, spinosad, which they determined to be non-synthetic and therefore allowed for organic production.

However, the Review Panel recommended that the formulation be Prohibited for use in organic production. The reason for prohibiting the product is that the inert ingredients 1,2 benzithisothiazolin and and ammonium lignosulfate fail into categories of prohibited inerts under OMRI's policy. Ammonium napthalene sulfonate and sodium naphthalene sulfonate are both unresolved at this point.

This decision indicates that your product does not meet organic standards based on OMRI's generic list and review policy and our understanding of the documentation you provided with your application. If you feel that we have erred in our decision, please provide additional written documentation to support your claim within 30 days of this letter's postmark.

OMRI encourages Dow AgroSciences to formulate a product with spinosad that clearly meets organic standards. A new formulation will require a separate application with complete documentation and the appropriate fees.

Prohibited listings are circulated to subscribing certifiers, but not to individual, corporate, or organizational subscribers. Please be aware that organic certifiers retain the right to make final certification decisions. These certifiers may choose to not accept OMRI's recommendation. Growers still need to contact their certifiers for information on the organic status of any given material. OMRI is not responsible for any losses that may occur as a result of this listing.

Again, thank you for your participation in the OMRI Brand Name Products Review Program. Please let us know if we can be of any further assistance.

Sincerely,

Brian Baker, Ph.D.
Technical Director

Organic Materials Review Institute
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